

### III. In the Claims (Marked Version)

Please cancel Claims 7, 8, 9, 13, 14, and 15 without prejudice or disclaimer. Such cancellation is not being made for any reason related to patentability under 35 USC §§101, 102, 103, and/or 112. No estoppel should result from said cancellation.

Please amend Claim 4 as follows:

4. (Amended) A method of treating [an inflammatory autoimmune disease] rheumatoid arthritis by modulating the reactivity of lymphocytes associated with said disease, comprising the step of administering a pharmaceutical composition comprising an effective amount of [HP] HC gp-39 or fragments thereof, and a pharmaceutically acceptable carrier, wherein said lymphocytes are reactive to antigens other than HC gp-39 which are present in the same tissue as HC gp-39.

Please add the following Claim:

16. A method of treating an autoimmune disease by modulating the reactivity of lymphocytes associated with said disease, comprising the step of administering a pharmaceutical composition comprising an effective amount of HC gp-39 or fragments thereof, and a pharmaceutically acceptable carrier, wherein said lymphocytes are reactive to antigens other than HC gp-39 which are present in the same tissue as HC gp-39.

### **III. In the Specification (Marked Version)**

Please insert - -

#### **Related Application**

This application is a continuation of U.S. Pat. App. No. 619,645, now U.S. Pat. No. 5,736,507.- -

On page 1, line 2, as a new line.

Please insert - -one or more of- - on page 7, line 20, of the originally submitted specification, after the word "in".

### **IV. Remarks**

#### **A. Typographical Corrections**

Applicants have made numerous amendments to correct typographical errors noted by the Examiner. These typographical errors do not alter the scope of the appended claims. Further, the correction of the typographical errors was not done for any reason related to patentability under 35 USC §§101, 102, 103, and/or 112. No estoppel should result from these amendments.

#### **B. Objections Under 37 CFR 1.75(d)(1) and MPEP §608.01(o)**

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. The Examiner contends that "wherein said fragments are selected from one or more of" SEQ ID NOs 1-8 and "wherein said fragments are selected from one or more of" SEQ ID NOs 5-8 is not supported by the specification. Applicants have amended the paragraph on page 7, lines 19-24 to more clearly point out Applicants'

intended disclosure. No estoppel should result from this amendment. Accordingly, Applicants respectfully request reconsideration.

**C. 35 USC §112, 1<sup>st</sup> ¶**

**1. Enablement**

Claims 4-15 stand rejected under 35 USC §112, 1<sup>st</sup> ¶, for not being enabled. Applicant has amended the claims and added new claims in support of enablement from the specification. In the specification, beginning on line 24 of page 3, studies indicate that the HC gp-39 is being expressed under numerous inflammatory autoimmune conditions. Prior art studies indicate that HC gp-39 is expressed under immune conditions in which maturation occurs, indicating that potentially in all inflammatory autoimmune diseases HC gp-39 can be found. (Krause S. W. et al, 1996, Journal of Leukoc. Biol., 60, 540). This indicates that while HC gp-39 may not be the direct cause of the inflammation associated disease, it is a result of the localized inflammation.

The Examiner has stated that the invention is enabled as to rheumatoid arthritis. Therefore, as the induction of HCgp-39 reactive modulator cells is beneficial for rheumatoid arthritis, for the unwanted immunological activity resulting in expressing HC gp-39, it necessarily follows that it would be beneficial for other diseases in which the immunological activity results in expression of HC gp-39. Accordingly, enablement of the invention has been provided.

Applicants would also point out that Claims 10-12 are not limited to a method for treating, but claim a method for modulating the reactivity of lymphocytes that are reactive to antigens other than HC gp-39 which are present in the same tissue as HC gp-39. Accordingly, Applicants respectfully request reconsideration.

## 2. Written Description

Claims 4-15 stand rejected by the Examiner under 35 U.S.C. § 112, first paragraph as containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. The Examiner keys on the fact that the written description of the invention does not provide or enable a method of treating any inflammatory autoimmune disease by "modulating the reactivity of lymphocytes comprising the effective amount of any fragment thereof of any IIP gp-39 and a pharmaceutical acceptable carrier, wherein said lymphocytes are reacted to any antigens other than HC gp-39 which are present in the same tissue as HC gp-39. Applicants have amended the Claims.

Further, the specification, beginning on page 10, line 2, through page 12, line 30, clearly illustrates that treatment with HC-gp-39 can trigger modulatory or regulatory mechanisms that interfere with the induction of arthritis with the use of a non-related antigen. Therefore, Applicants have provided a written description of modulation when administering HC gp-39. Accordingly, Applicants respectfully request reconsideration.

### D. 35 USC §112, 2<sup>nd</sup> ¶

Claims 11-15 stand rejected by the Examiner under 35 U.S.C § 112, second paragraph, as being indefinite or failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Examiner contends that the recitation of "said autoimmune disease is rheumatoid arthritis" in claims 13-15 has no basis in claims 10-12. Claims 13-15 have been cancelled, without prejudice or disclaimer.

**E. 35 USC §102****1. §102(b)****a. the 1997 article**

Claims 4-15 stand rejected by the 1997 article by Verheijden et al. (the 1997 article) titled Arthritis and Rheumatism. The Examiner contends that the teachings of the 1997 article would inherently disclose Applicant's invention. Applicants do not agree with the Examiner's contention. However, Applicants have amended the specification to claim proper priority from United States Patent No. 5,736,507 (the '507 patent). The '507 patent issued from a PCT filed October 25, 1995.

The instant application is entitled to priority and continuing status from the '507 patent.

- 1) The instant application is an application for an invention which is also disclosed in the first application.
- 2) The instant application was copending with the '507 patent.
- 3) The specification of the instant application has been amended to contain a specific reference to the '507 patent.
- 4) The instant application shares inventive entity in Helena Boots.
- 5) The application was filed before November 29, 2000.
- 6) N/A

Accordingly, pursuant to MPEP §201.11, the instant application is entitled to priority of the '507 patent.

The '507 patent was filed before the 1997 article. Therefore, the '1997 article is not prior art to the instant patent application.

**b. the '517 publication**

Claims 4-15 stand rejected under 35 USC §102(b) as being anticipated by WO 96/13517 (the '517 publication). The specification has been amended to claim priority to this application. Therefore, this application is not prior art and the rejection should be removed.

**2. 102(e)**

Claims 4-15 stand rejected under 35 USC §102(e) as being anticipated by the '507 patent. The specification has been amended to claim priority to this patent. Therefore, the rejection should be removed.

**V. Conclusion**

Applicants respectfully request reconsideration of the rejections in light of this response. The application is believed in a condition for allowance and Applicants respectfully request such action. Applicants respectfully request the examiner contact the undersigned attorney for an interview to expedite prosecution of the case. Please charge deposit account number 02-2334 for any required fees.

Date:

12/10/02

Sincerely,

  
William P. Ramey, III

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